NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS CORPORATION; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civ. No. 04-4473 (HAA) (ES)
NOVARTIS CORPORATION; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. WATSON LABORATORIES, INC. and WATSON PHARMACEUTICALS, INC., Defendants.	Civ. No. 06-1130 (HAA) (ES) **OPINION and ORDER**

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Ackerman, Senior District Judge:

This matter comes before the Court on the motion filed on March 27, 2007, (Docket No. 42), by Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG (hereinafter collectively "Plaintiffs" or "Novartis")[1] seeking a preliminary injunction against Teva Pharmaceuticals USA, Inc. (hereinafter "Defendant" or "Teva"). Novartis seeks to enjoin Teva from marketing generic versions of Novartis's product Lotrel®, a prescription drug medication for the treatment of hypertension covered by U.S. Patent No. 6,162,802 ("the '802 patent"). For the reasons stated below, Novartis's motion for preliminary injunction is DENIED.

[1] "Plaintiffs" or "Novartis" as used herein also includes one of Novartis's predecessor companies, Ciba-Geigy Corporation.

I. INTRODUCTION

A. Factual Background and Procedural History[2]

The '802 patent, entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor," was filed on March 10, 1992. On December 19, 2000, after more than eight years of prosecution, the United States Patent and Trademark Office ("PTO") issued the '802 patent to Ciba-Geigy Corp., a predecessor of Novartis, as assignee of inventors Joseph Papa and Marc M.J. Henis. Generally, the '802 patent claims methods for the treatment of cardiovascular disorders, including hypertension, and pharmaceutical compositions combining two different anti-hypertensive agents, amlodipine and benazepril.

On March 3, 1995, Novartis received approval from the FDA to market Lotrel in six dosage strengths: 2.5/10 mg (amlodipine besylate/benazepril hydrochloride), 5/10 mg, 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg. (Pl. Br. at 4.) Lotrel is approved for the treatment of hypertension and has been marketed in the United States since its approval. (*Id.*) In accordance with 21 U.S.C. § 355(b)(1), Novartis filed with the FDA the patent numbers and expiration dates for each patent covering Lotrel. (*Id.* at 5.) The FDA publishes this information in a list of innovator drug products and their related patent information called *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." 21 U.S.C. § 355(j)(7)(A). The Orange Book listed four patents for Lotrel; however, the '802 patent

[2] The following background discussion is drawn from the parties' submissions and does not constitute findings of fact.

represents the only remaining unexpired patent, and the only patent-at-issue in this matter.[3]

On June 8, 2004, Teva filed an Abbreviated New Drug Application ("ANDA"), No. 77-179, pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j), to market generic equivalents of four of Novartis's Lotrel drug products before the expiration of the '802 patent.[4] (Pl. Br. at 2.) Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e., in a "Paragraph IV Certification," Teva certified in its ANDA that "to the best of its knowledge" its drug formulations would not infringe the '802 patent or that the '802 patent is invalid and unenforceable.[5] As required by statute, Teva served Novartis on or about August 6, 2004 with a notice of its position and intent to seek approval from the FDA. 35 U.S.C. § 355(j)(5)(B)(i); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001). Novartis timely filed the instant lawsuit on September 16, 2004, pursuant to 35 U.S.C. § 217(e)(2), which gave rise to an automatic 30-month stay under the Hatch-Waxman Act,[6] during which time the FDA could

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[3] In addition to the '802 patent, the Orange Book listed the following U.S. Patent Numbers for Lotrel: 4,410,510 ("the '510 patent") covering benazepril hydrochloride; 4,572,909 ("the '909 patent"); and 4,879,303 ("the '303 patent"). The '909 and '303 patents, directed to the amlodipine component of Lotrel, are owned by Pfizer Inc. ("Pfizer"). Novartis owned the '510 patent, and licensed the right to use the '909 and '303 patents from Pfizer. (Pl. Br. at 5.)

[4] Teva sought approval to market generic versions of the 2.5/10 mg, 5/10 mg, 5/20 mg, and 10/20 mg dosage strengths. (Pl. Br. at 10 n.4.)

[5] Teva's ANDA could not be approved until the '909 and '303 patents expired because its ANDA did not challenge either of these patents via a Paragraph IV certification. The '909 patent expired on July 31, 2006. On March 22, 2007, only a few days before the '303 patent's March 25, 2007 expiration date, the Federal Circuit held that the '303 patent was invalid for obviousness and unenforceable. *Pfizer v. Apotex*, 480 F.3d 1348, 1372 (Fed. Cir. 2007), *reh'g and reh'g en banc denied*, ___ F.3d ___, No. 2006-1216, 2007 WL 1464593 (Fed. Cir. May 21, 2007).

[6] Commonly referred to as the "Hatch-Waxman Act," this legislation is formally known as The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98

not grant Teva final approval to market its proposed products. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA granted tentative approval to Teva's ANDA on July 11, 2006. On or about February 6, 2007, the statutory 30-month stay expired. *Id.*

On March 21, 2007, approximately six weeks after the termination of the statutory 30-month stay, Novartis sent a letter to this Court, requesting emergent relief, apparently fearing that Teva was prepared to launch its generic products at-risk as early as March 26, 2007.[7] In a March 22, 2007 Order, this Court denied Novartis's request for a conference to be held on or before March 23, 2007. This Court was critical of Novartis's alleged need for emergent relief on the supposed precipice of a possible launch by Teva when the dates of the '303 patent expiration and the 30-month stay had been known to all parties for multiple years.

Soon thereafter, on March 27, 2007, Novartis filed a motion for preliminary injunction. In this motion, Novartis requested that Teva be enjoined from "making, using, selling, or offering to sell products falling under its [ANDA] that seeks FDA approval to market a generic equivalent of Novartis'[s] product Lotrel.®" (Pl. Proposed Order, at *2.) Novartis asserted that the FDA had the authority to grant final approval to Teva's generic versions of Lotrel because the 30-month stay and the two patents covering the amlodipine component of Lotrel (the '909 and '303 patents), neither of which Teva challenged, had expired. (Pl. Br. at 11.)

Accordingly, on March 27, 2007, this Court approved a briefing schedule, which set a

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Stat. 1585 (1984) (codified at scattered sections of 21, 35, and 42 U.S.C.).

[7] Notwithstanding the fact that the Federal Circuit had already decided on March 22, 2007, that the '303 patent was unenforceable, *Pfizer v. Apotex,* 480 F.3d 1348, 1372 (Fed. Cir. 2007), the March 26, 2007 date, in Novartis's estimation, was significant because the '303 patent was set to expire on March 25, 2007.

May 30, 2007, hearing date. By April 24, 2007 the parties had submitted all briefing in this matter, but on May 15, the Court informed the parties that the hearing had to be adjourned until July 2, 2007, at the earliest. On the following day, May 16, 2007, the parties contacted the Court and agreed to a July 11 hearing date.

Later that week, on Friday, May 18, 2007, the FDA granted final approval to Teva's ANDA. On Saturday, May 19, 2007, Novartis filed with this Court a motion for a temporary restraining order ("TRO") (Docket No. 54) to enjoin Teva from marketing its generic versions of Lotrel. Apparently, Novartis had learned on Friday evening that Teva launched its generic versions of Lotrel immediately after Teva obtained final approval from the FDA that same day. (Novartis's March 19, 2007 TRO Br., at *2). Novartis asserted that Teva had already "begun taking orders and shipping for delivery on Monday, May 21, 2007." (*Id.*) On Saturday, May 19, 2007, District Judge Dennis M. Cavanaugh, granted Novartis's proposed TRO, (Docket No. 56), temporarily restraining Teva "from making, using, selling, or offering to sell products under its [ANDA No. 77-179]." (J. Cavanaugh's March 19, 2007 Order, at *2.) In addition, Teva was ordered, *inter alia*, to execute a recall of all of its products from the market. (*Id.* at *3.) Judge Cavanaugh further ordered that the parties appear before the Court on Monday, May 21 at 11:00 a.m. to further address the TRO and other emergent relief. (*Id.* at *4.)

At the May 21, 2007 hearing, Judge Cavanaugh vacated the May 19, 2007 TRO, and ordered both parties not to sell or offer to sell further generic products, beyond what has already been commercialized, until at least Tuesday, May 29, 2007. In other words, Judge Cavanaugh did not require Teva to recall what it sold on Friday and Saturday before the TRO was entered. A May 23, 2007 Order, signed by this Court, memorialized that ruling. (Docket No. 58.) On

Tuesday, May 29, 2007, this Court conducted a conference call with the parties. Both parties informed the Court that they would be amenable to the continuation of the existing restraining order pending this Court's preliminary injunction determination. Thereafter, this Court informed that parties that the preliminary injunction motion would be decided on the papers alone, and ordered that the TRO remain in effect until further order of the Court. (Docket No. 64.)

II. DISCUSSION

A. Preliminary Injunction Standard

This Court may grant an injunction to "prevent the violation of any right secured by patent." 35 U.S.C. § 283. By its terms, 35 U.S.C. § 283 makes the grant of an injunction discretionary. *See Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (noting that a preliminary injunction is "a drastic and extraordinary remedy that is not to be routinely granted."); *see also Bateman v. Ford Motor Co.*, 310 F.2d 805, 808 (3d Cir. 1962) ("It has been so well stated that upon an application for a preliminary injunction to doubt is to deny.") (citations and internal quotation marks omitted). However, this Court's "discretion is not absolute and must be measured against the standards governing the issuance of an injunction." *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988); *see also Purdue Pharm. L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001) ("An abuse of discretion may be shown if the district court made a clear error of judgment, or based its decision on an erroneous legal conclusion or clearly erroneous factual findings."). Nevertheless, this Court is mindful--and implores the parties to remain fully cognizant--that "all findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits." *Purdue Pharm.*, 237 F.3d at 1363.

To obtain a preliminary injunction, a movant must demonstrate: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *see also Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994) ("The burden is always on the movant to show entitlement to a preliminary injunction.") "These factors, taken individually, are not dispositive." *Hybritech*, 849 F.2d at 1451. Accordingly, the Federal Circuit has counseled district courts to "weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Id.*; *see also Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996).[8]

However, irrespective of how the court resolves the third and fourth factors, the movant must demonstrate the existence of the first two before the court can grant a motion for a preliminary injunction. *See Reebok Int'l*, 32 F.3d at 1555-56; *see also Amazon.com*, 239 F.3d at 1350 ("Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, i.e., likelihood of success on the merits and irreparable harm."). Although, from the perspective of appellate review, "it is always preferable that a district court make findings regarding each of the four factors," this Court may deny the motion without articulating findings respecting the other factors if Novartis fails to

[8] Because Novartis bears the burden of showing entitlement to a preliminary injunction, challenges during a preliminary injunction to the validity of a patent "can be successful . . . on evidence that would not suffice to support a judgment of invalidity at trial." *Amazon.com*, 239 F.3d at 1358. "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." *Id.* at 1359.

establish either of the first two factors. *Reebok Int'l*, 32 F.3d at 1555.

B. Novartis's Motion for a Preliminary Injunction

1. Reasonable Likelihood of Success on the Merits

To show an overall likelihood of success on the merits, Novartis must demonstrate at the preliminary injunction stage that "in light of the presumptions and burdens that will inhere at trial on the merits,"[9] (1) Novartis will likely prove that Teva infringes one or more claims of the '802 patent, and (2) Novartis's infringement claim will likely withstand Teva's challenges to the validity and enforcement of the '802 patent. *Amazon.com*, 239 F.3d at 1350. A preliminary injunction should not issue if Teva can raise "a substantial question concerning either infringement or validity, i.e., asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit.'" *Id.* at 1350-51 ("[I]n cases involving multiple patent claims, to demonstrate a likelihood of success on the merits, the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer."). In other words, if Teva raises a "substantial question" of validity or infringement, then Novartis must produce countervailing evidence demonstrating that those defenses "lack[] substantial merit." *Purdue Pharm.*, 237 F.3d at 1363 (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)).

a. Infringement

First, this Court will address whether Novartis is likely to prove that Teva infringes one

[9] For example, an issued patent is presumed valid at every stage of the litigation, including the preliminary injunction stage. 35 U.S.C. § 282; *see also Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998).

or more claims of the '802 patent. To evaluate infringement, a Court generally must engage in a two-step analysis: (1) construe the patent's claims to ascertain their proper scope, and (2) compare the construed claims to the allegedly infringing products or processes to determine whether those products or processes fall within the scope of those claims literally or under the doctrine of equivalents. *Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1466 (Fed. Cir. 1998) (en banc). As a question of law, claim construction is a task for a judge, not a jury. *Id.* at 1454-56; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc) ("[I]nterpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court."). For the purposes of a preliminary injunction, this Court may construe claims of the '802 patent in order to evaluate Teva's likelihood of infringement. However, this Court need not, and will not, arrive at a final and conclusive claim construction. *See Sofamor*, 74 F.3d at 1221. This Court's claim construction is not binding at trial. *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 (Fed. Cir. 1990). To the extent that this opinion appears to establish final findings of fact or law, the parties again are reminded that all findings, for the purposes of the instant preliminary injunction motion, are themselves preliminary.

i. General Principles of Claim Construction

When construing disputed claims, it is appropriate primarily to look to the intrinsic evidence in the record. *Metrologic Instruments, Inc. v. Symbol Technologies, Inc.*, 460 F. Supp. 2d 571, 582-83 (D.N.J. 2006). Intrinsic evidence includes "the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Id.* (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The first step in a claim construction

analysis requires a court to examine the words of the claim or claims themselves to define the proper scope of the claimed invention. *Id.* The Federal Circuit reminds us that "[i]t is a bedrock principle of patent law that the claims of a patent define the innovation to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (citation and quotation marks omitted); *see also Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1336 (Fed. Cir. 2004) ("It is axiomatic that the claims mark the outer boundaries of the patent right to exclude."). However, the "critical challenge" a court faces when construing claims is "determin[ing] the meaning of the claims, i.e., their scope." *Astrazeneca AB*, 384 F.3d at 1336.

Generally, the words of a claim are given their ordinary and customary meaning, as viewed by a person of ordinary skill in the art in question at the time of the invention. *Phillips*, 415 F.3d at 1312-13; *id.* at 1313 ("It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed."). However, the court will not accord a claim term its ordinary meaning in two situations. "The first arises if the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term. The second is where the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999) (internal citations omitted); *see also Phillips*, 415 F.3d at 1316.

Although an invention is defined by a patent's claims, they "do not stand alone." *Phillips*, 415 F.3d at 1315. Claims "are part of 'a fully integrated written instrument,'" *id.* at 1315 (citing *Markman*, 52 F.3d at 978), consisting principally of a written description of the

invention, 35 U.S.C. § 112 para. 1, often referred to as the specification,[10] and concluding with the claims, 35 U.S.C. § 112 para. 2. "For that reason, claims 'must be read in view of the specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313; *see also Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.") (citation omitted). Thus, the second step in a claim construction analysis requires examination of the specification.

It is often recognized that a patent's specification is "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315; *see also United States v. Adams*, 383 U.S. 39, 49 (1966) ("[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."). In addition to defining terms, the specification "teaches about the problems solved by the claimed invention, the way the claimed invention solves those problems, and the prior art that relates to the invention. These teachings provide valuable context for the meaning of the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1554 (Fed. Cir. 1997), *abrogated on other grounds, Cybor Corp.*, 138 F.3d at 1456. Pursuant to 35 U.S.C. § 112, paragraph 1, a patent's

[10] As defined by 35 U.S.C. § 112, the specification of a patent is technically the written description of the disclosed invention plus the claims as originally filed. 35 U.S.C. § 112 para. 2. However, as used widely by courts and practitioners, the term "specification" herein refers only to the written description of the invention, excluding the claims.

specification must describe the claimed invention in "full, clear, concise, and exact terms." This written description requirement, the Federal Circuit has recognized, maintains a "close kinship" with the meaning of a patent's claims. *Phillips*, 415 F.3d at 1316. "In light of the statutory directive that the inventor provide 'full' and 'exact' description of the claimed invention, the specification necessarily informs the proper construction of the claims." *Id.*; 5A-18 Donald S. Chisum, Chisum on Patents § 18.03(2)(c) (2006). Notably, in some cases, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Phillips*, 415 F.3d at 1316. In such instances, "the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." *Id.* (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001)).

The third step in claim construction entails consideration of a patent's prosecution history. The prosecution history of a patent, also known as the "file wrapper," "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be."[11] *Phillips*, 415 F.3d at 1317. When construing claims, one of the purposes of consulting the prosecution history is to "exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580 (Fed. Cir. 1988)

[11] A patent's prosecution history "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. This record also includes "any express representations made by the applicant regarding the scope of the claims." *Vitronics*, 90 F.3d at 1582.

(citation omitted). Importantly, "where the patentee has *unequivocally disavowed* a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g., Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (emphasis added); *see also id.* ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution."). For example, during the application process, a patent examiner may require the applicant to limit the scope of his or her proposed claims so as not to include prior art within their ambit. An applicant may also limit the scope of his or her proposed claims in the process of distinguishing his or her invention over the prior art in order to obtain a patent. When an applicant surrenders or disclaims subject matter in this manner, the disclaimer becomes part of the prosecution history. If the application ultimately issues as a patent, the patent holder is bound by his or her prior disclaimers. *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed. Cir. 1998) ("[E]xplicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim."). Thus, examination of a patent's prosecution history and the application of prosecution disclaimer is a helpful tool during claim construction as it "ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005).

However, a court's reliance on prosecution history, the Federal Circuit has warned, must be tempered with the recognition that a "prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." *Phillips,*

415 F.3d at 1317. As such, it is important to acknowledge that a prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Accordingly, prosecution disclaimer is not appropriate in instances "where the alleged disavowal of claim scope is ambiguous," or where remarks made by an inventor to overcome a rejection may be viewed "as amenable to multiple reasonable interpretations." *Omega*, 334 F.3d at 1324 (citing *Northern Telecom Ltd. v. Samsung Electronics Co.*, 215 F.3d 1281, 1293-95 (Fed. Cir. 2000)). Thus, "for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325-26.

It is important to note, however, that there is a distinction between construing the claims in light of their prosecution history and applying the doctrine of prosecution history estoppel.[12] Courts consult the prosecution history of a patent during claim construction, while they *apply* the doctrine of prosecution history estoppel only during trial as a measure of preventing a patentee from improperly benefitting from the doctrine of equivalents.[13] *Altech Controls Corp. v. E.I.L.*

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[12] The doctrine of prosecution history estoppel "precludes a patent owner in an infringement suit from obtaining a construction of a claim that would in effect resurrect subject matter surrendered during the course of proceedings in the Patent and Trademark Office." 5A-18 Chisum, *supra*, § 18.05; *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 564-65 (Fed. Cir. 2000) (en banc) ("The logic of prosecution history estoppel is that the patentee, during prosecution, has created a record that fairly notifies the public that the patentee has surrendered the right to claim particular matter as within the reach of the patent."), *vacated & remanded on other grounds*, 535 U.S. 722 (2002), *on remand*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc), *cert. denied*, 541 U.S. 988, 124 (2004); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999).

[13] The doctrine of equivalents "allows a patent owner to hold as an infringement a product or process that does not [fall within] the literal terms of a patent's claim but performs substantially the same function in substantially the same way to obtain the same result as the claimed subject matter." 5A-18 Chisum, supra, § 18.04 (footnote omitted). The doctrine is a

Instruments, Inc., 71 F. Supp. 2d 677, 680 (S.D. Tex. 1999) ("Prosecution history estoppel imposes a legal limitation on the application of the doctrine of equivalents in excluding from the range of equivalents any subject matter surrendered during the prosecution of the application for the patent . . . ."). The Federal Circuit has cautioned district courts not to confuse "following the statements in the prosecution history in defining a claim term, [with] the doctrine of prosecution history estoppel, which limits expansion of the protection under the doctrine of equivalents when a claim has been distinguished over relevant prior art." *Spectrum*, 164 F.3d at 1378 n. 2.

Lastly, a court may rely on extrinsic evidence, such as expert and inventor testimony, dictionaries, and learned treatises, if an analysis of the intrinsic evidence does not give clarity to a disputed claim term. *Vitronics*, 90 F.3d at 1583 (noting, however, that "[i]n most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term"). Nevertheless, a court should not rely on extrinsic evidence when the public record unambiguously defines the scope of the claimed invention. "The claims, specification, and file history, rather than extrinsic evidence, constitute the public record . . . on which the public is entitled to rely." *Id.*

The sequence in which the various sources are consulted is not important; rather, the appropriate weight must be given to those sources "in light of the statutes and policies that inform patent law." *Phillips*, 415 F.3d at 1324.

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response to the difficulties in capturing an invention with words. For a court only to conduct literal infringement analysis and confine an invention strictly to its written application may, in some instances, be unfair to the inventor. The Supreme Court observed in *Festo* that "the nature of language makes it impossible to capture the essence of a thing in a patent application. . . . [It] may not capture every nuance of the invention or describe with complete precision the range of its novelty." *Festo*, 535 U.S. at 731.

ii. Claims of the '802 Patent

In this case, Novartis accuses Teva of infringing claims 1, 2 and 19 of the '802 patent under 35 U.S.C. § 271(a).[14] (Pl. Br. at 3.) However, all claims of the '802 patent are implicated as they are all either directly or indirectly dependent on claims 1 and 19, the patent's only independent claims. Novartis asserts that Teva infringes the '802 patent directly and indirectly. (*Id.* at 13-22.)

By way of background, claims 1-17 of the '802 patent are directed to a method of treatment of various conditions. This method of treatment utilizes the administration of a combination of benazepril, an angiotensin converting enzyme inhibitor ("ACEI" or "ACE inhibitor"), and amlodipine, a calcium channel blocker ("CCB").[15] Claims 2-16 are all dependent on claim 1, which reads as follows:

> 1. A method of treating a condition selected from the group consisting of hypertension, congestive heart failure, angina, myocardial infarction, artherosclerosis, diabetic nephropathy, diabetic cardiac myopathy, renal insufficiency, peripheral vascular disease, left ventricular hypertrophy, cognitive dysfunction, stroke, and headache, in a human in need thereof, consisting of administering a daily dose of

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[14] Section 271(a) provides "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."

[15] Apparently, ACEIs and CCBs both lower blood pressure, but via "different mechanisms of vasodilating action." (Epstein Decl. at ¶ 24.) "CCBs work by inhibiting the entry of calcium ions into smooth muscle cells and by inhibiting the influx and release of calcium ions from the sarcoplasmic reticulum. As a result, muscle contraction is prevented and vascular resistance is reduced." (*Id.* at ¶ 25.) "ACE inhibitors function by inhibiting the conversion of inactive angiotensin I peptide to active angiotensin II peptide. Consequently, the active angiotensin II peptide mediates constriction of a patient's arteries. As a result of inhibiting this conversion, there is a decrease in the vasoconstriction, and consequently, a decrease in blood pressure." (*Id.* at ¶ 26.)

> (a) benazepril, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 2 mg to 80 mg of benazepril hydrochloride; and
> (b) amlodipine, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 1 mg to 20 mg of amlodipine free base,
> wherein the ratio of benazepril to amlodipine corresponds to a weight ratio of from 1:1 to 8:1 of benazepril hydrochloride to amlodipine free base.

('802 patent, col.5, ll. 6-21.)[16] Dependent claims 2, 3, 17, and 18 are also of particular relevance to the instant dispute. *See Pods, Inc. v. Porta Stor, Inc. et al.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007) (noting that a court is "not limited to considering just the language of" a particular claim in dispute "because '[o]ther claims of the patent in question, both asserted and unasserted, [are] valuable sources of enlightenment as to the meaning of a claim term.'") (citing *Phillips*, 415 F.3d at 1314). These method claims provide:

> 2. The method of claim 1 wherein the benazepril and the amlodipine are administered in a single dosage form, such that the benazepril and amlodipine are **physically separated** from each other.
>
> 3. The method of claim 2 wherein the single dosage form comprises a capsule comprising within it (a) a coated compressed table of benazepril and (b) amlodipine powder.
>
> . . . .
>
> 17. The method of claim 1 wherein the benazepril is administered in a first formulation which is free of the amlodipine and the amlodipine is administered in a second formulation which is free of the benazepril.
>
> 18. The method of claim 17 wherein said first formulation and said

[16] Claim 1 and all claims subsequently cited herein include any PTO-approved corrections to typographical errors that originally appeared in the printed patent. (*See* Certificate of Correction, Woodard Decl. at 617-20.)

> second formulation are administered within about one hour of each other.

('802 patent, col. 5, ll. 22-28; col. 6, ll. 1-7 (emphasis added).)[17]

Claims 19-33 of the '802 patent are directed to a pharmaceutical composition consisting essentially of a combination of benazepril and amlodipine. Claims 20-33 are all dependent on claim 19, which reads as follows:

> 19. A pharmaceutical composition consisting essentially of a daily dose of
>
> (a) benazepril, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 2 mg to 80 mg of benazepril hydrochloride; and
>
> (b) amlodipine, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 1 mg to 20 mg to amlodipine free base,
>
> wherein the ratio of benazepril to amlodipine corresponds to a weight ratio of from 1:1 to 8:1 of benazepril hydrochloride to amlodipine free base, such that the benazepril and the amlodipine are **physically separated** from one another.

('802 patent, col. 6, ll. 8-19 (emphasis added).)[18]

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[17] Claims 4-16 of the '802 patent, not reproduced herein, provide additional limitations to the method of treatment claims cited above. For example, these dependent claims further limit the claimed method of treatment to specific "amounts" or daily "dosage ranges," (claims 5, 14-16), and to specific "ratios" or "weight ratios" of the two formulations, benazepril and amlodipine, (claims 6-7, 11-13.). Other claims limit the method of treatment to a benazepril *hydrochloride* formulation or an amlodipine *besylate* formulation, (claims 4, 8-10). Naturally, the foregoing description of claims 4-16 in no way represents a claim construction on the part of this Court; this summary is provided merely for the purposes of background.

[18] Claims 20-33 of the '802 patent, not reproduced herein, provide additional limitations to the composition claim cited above. For example, these dependent claims further limit the claimed pharmaceutical composition to specific "amounts," (claims 26-28), and to specific "ratios" or "weight ratios," between the two formulations, benazepril and amlodipine, (claims 23-25). Claim 29 limits the composition to a capsule form "comprising within it (a) a coated compressed tablet of benazepril, and (b) amlodipine powder." The remaining claims limit the pharmaceutical compositions to a benazepril *hydrochloride* formulation or an amlodipine *besylate* formulation, (claims 20-22, 30-33). Again, the foregoing description of claims 20-33

Novartis argues that "[t]he administration of Teva's Products to patients with hypertension would directly infringe claim 1 of the '802 patent." (Pl. Br. at 13; *see also id.* at 21-22 (asserting that Teva *indirectly* infringes claim 1 of the '802 patent by inducement and contribution).) It is undisputed, Novartis asserts, that Teva seeks to market and sell its products for the approved indication of treating hypertension to a human being in need thereof and in dosages meeting the required dose and ratio limitations for benazepril and amlodipine set forth in claim 1. (Pl. Br. at 13.) The parties' claim construction dispute, however, centers on two primary issues: (1) whether any '802 patent claim covers a single dosage form where benazepril and amlodipine are *not* "physically separated," and the meaning thereof; and (2) the meaning of the term "daily dose" as it is used in the '802 patent.[19]

iii. "Physically Separated"

With regard to the "physically separated" limitation, this Court must first consider whether *any* '802 patent claim covers a single dosage form where benazepril and amlodipine are *not* "physically separated." Teva would have this Court answer this question in the negative and hold that the asserted '802 patent claims each require that the benazepril and amlodipine, when in a single dosage form, be "physically separated." (Def. Br. at 3 (hereinafter "the physically separated requirement").) According to Teva, "this requirement is explicit" with regard to

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does not represent a claim construction, but rather is provided for background purposes.

[19] For the reasons discussed below, the Court need not, and will not, engage in a preliminary claim construction of claim 1 with regard to the meaning of "daily dose," a term that is not explicitly defined in the claims or specification. (Pl. Br. at 13.)

asserted claims 2, 8-16 and 19-33. (*Id.*)[20] Acknowledging that the term "physically separated" does not appear in the language of claim 1, Teva argues that the physically separated requirement nevertheless applies to claim 1 because claim 1 "is dictated by the *express disclaimer* of broader scope made by Novartis in the specification and prosecution history of the '802 patent." (*Id.* (emphasis in original).) Pursuant to this interpretation, Teva argues that it does not infringe any claims of the '802 patent because the generic formulation that is the subject of its ANDA is limited to single dosage forms where the amlodipine and benazepril "are mixed together, and thus *not* physically separated from each other." (*Id.* (emphasis in original).) According to Teva, its formulation "is simply a mixture of a granulate of benazepril with a powder of amlodipine," and critically, "[t]here is no barrier" between the drugs to keep them apart. (*Id.* at 9.) Thus, in addition to determining whether claim 1 includes single dosage forms where benazepril and amlodipine are not physically separated from another, this Court must then determine the meaning of the term "physically separated." This Court will address the former issue first.

(1) Application of the "physically separated" requirement to all claims of the patent.

Novartis asserts that treating hypertension using Teva's generic formulation "irrefutably" will infringe claim 1. (Pl. Reply Br. at 1.) According to Novartis, Teva's claim construction argument is "a futile effort to rewrite claim 1 to include the 'physically separated' limitation" that has "no basis in law or the language of the claims." (*Id.* at 1-2.) Specifically, Novartis argues

[20] Although Teva suggests that claims 8-16 explicitly require "physical separation," this Court believes that Teva intended to refer to claims 3-7. Unlike claims 8-16, claims 3-7 are either directly or indirectly dependent on claim 2, which itself includes the "physically separated" language explicitly. Claims 8-16, as well as 17-18, are all either directly or indirectly dependent on claim 1.

that: (1) Teva's proposed construction violates the principles of claim differentiation; and (2) Novartis did not explicitly disavow subject matter in the specification or prosecution history. Additionally, by asserting infringement of claims 2 and 19-28, (Pl. Reply Br. at 7-9), Novartis argues--at least implicitly--that, even under Teva's proposed construction, Teva's products would infringe claim 1 and all other claims dependent thereon. This is because, despite Teva's assertion that its products are "fundamentally different from the formulation claimed in the '802 patent," (Def. Br. at 3), Novartis asserts that "Teva's manufacturing process necessarily results in the physical separation of benazepril and amlodipine." (Pl. Reply Br. at 7.) Novartis proposes a definition for the term "physically separated," which, it believes, would cover Teva's generic formulations.

In the '802 patent, the term "physically separated" appears in claims 2 and 19, and in one location in the written description. In relevant part, the written description provides:

> Benazepril and amlodipine are physically incompatible substances. Hence, if incorporated into a single dosage form **they must be kept physically separated**. This may be accomplished in any of the myriad ways known in the art, such as bi-layered tablets, coated pellets of one agent incorporated into a tablet of the other, separately coated pellets of one agent in capsule together with powder of the other agent, each agent microencapsulated separately and then blended together for use in a tablet or capsule, use of a dual or multiple compartment transdermal device, etc. Due to the incompatibility, combination products of the two agents in an injectable solution are not really acceptable. For convenience purposes, a coated compressed tablet of benazepril together with amlodipine powder in a capsule has been found to be the most desirable oral form.

('802 patent, col. 3, ll. 51-66 (emphasis added).) As noted above, claim 2, a method of treatment claim, covers "[t]he method of claim 1 wherein the benazepril and the amlodipine are administered in a single dosage form, such that the benazepril and amlodipine are **physically**

separated from each other." ('802 patent, col. 5, ll. 22-25 (emphasis added).) Lastly, the pharmaceutical composition claimed in claim 19 consists essentially of a daily dose of benazepril and amlodipine, in specific ratios, "such that the benazepril and the amlodipine are **physically separated** from one another." ('802 patent, col. 6, ll. 18-19 (emphasis added).) It should be noted that claims 20-33 are all either directly or indirectly dependent on claim 19, therefore the term "physically separated" must be attributed to those claims as well. The same applies to claims 3-7, which are either directly or indirectly dependent on claim 2.

Critically, the term "physically separated" does not appear in claim 1 or in claims 8-18. The parties' primary dispute centers on whether this limitation must be attributed to all of the patent's claims. As discussed above, Novartis asserts that claim 1 covers all single dosage forms, whether physically separated or not. Teva, however, argues that the physically separated requirement applies to every claim, including claim 1, because the specification and prosecution history expressly disclaim any broader scope. Teva concedes that "claim 1 is broad enough to cover the separate administration of drugs *as well as* the use of a single dosage form." (Def. Br. at 11.) However, Teva argues that the term "dose" in claim 1 "simply cannot be construed to cover *all* single dosage forms." (*Id.* (emphasis in original).) According to Teva, the specification as a whole, and specifically the passage cited above, clearly indicate an express disavowal of scope of claim 1 and the entire patent. Teva relies principally on the statement in the specification that "[b]enazepril and amlodipine are physically incompatible substances," and, as such, "if incorporated into a single dosage form they must be kept physically separated." According to Teva, the impact of this statement is a complete disavowal of any "dose" in the entire patent, including claim 1, that extends to a single dose administration where benazepril and

amlodipine are *not* physically separated. In other words, to the extent a "dose" in claim 1 covers single dose administrations, it does not cover those that are not physically separated.

Not surprisingly, Novartis rejects Teva's argument, characterizing it as an attempt to "rewrite claim 1 to include the 'physically separated' limitation." (Pl. Reply Br. at 1.) According to Novartis, the specification does not include an explicit disavowal. Novartis asserts that "[t]he Federal Circuit has repeatedly held that adding extraneous limitations to a claim from the specification is improper." (*Id.* at 1-2 (citing *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("The written description . . . is not a substitute for, nor can it be used to rewrite, the chosen claim language.").)

This Court is well aware that it is considered to be a "cardinal sin" of patent law to read or import a limitation from the written description into the claims. *SciMed Life Sys.*, 242 F.3d at 1340; *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). Nevertheless, as discussed above, it is a settled principle of claim construction that a "specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Phillips*, 415 F.3d at 1316. Where language is "unequivocal," subject matter that otherwise could have been considered to fall with the scope of the claim language absent the disclaimer, is disclaimed. *SciMed Life Sys.*, 242 F.3d at 1344; *Teleflex*, 299 F.3d at 1324 ("[C]laim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope. "). Discussing several cases in which claims were given narrow construction in light of the written description, the Federal Circuit in

SciMed Life Systems explained that "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Sys.*, 242 F.3d at 1341. Thus, it is apparent to this Court that although reading limitations from the written description into claims is generally prohibited, in *some* instances the scope of a patent's claim may be appropriately limited by the written description. *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1310 (Fed. Cir. 2005) ("Our case law requires a textual 'hook' in the claim language for a limitation of this nature to be imposed."); *Johnson Worldwide*, 175 F.3d at 990 (noting that "there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction"). According to Teva, this approach is appropriate when construing the '802 patent. In this regard, and for the reasons discussed below, this Court finds that Teva has raised a substantial defense of noninfringement. Novartis has failed to produce countervailing evidence demonstrating that this defense "lacks substantial merit."

In *TAP Pharmaceutical Products, Inc. v. Owl Pharmaceuticals, L.L.C.*, a decision upon which Teva principally relies, the Federal Circuit affirmed a district court's construction of a claim term to include a limitation from the specification that did not appear in the claim itself. 419 F.3d 1346 (Fed. Cir. 2005). In relevant part, the claim at issue provided for "[a] prolonged release microcapsule for injection, which comprises *particles containing a water-soluble drug*, the particles being dispersed in a spherical microcapsule matrix . . . ." (*Id.* at 1353 (emphasis added).) According to the court, "the specification ma[de] clear that the phrase 'particles containing a water-soluble drug' [from the claim at issue] must be interpreted as requiring both a

drug and some substance in which to retain the drug." *Id.* The court noted with approval the district court's reasoning that "all of the 31 examples in the specification describe the use of particles containing a drug and a drug-retaining substance." *Id.* Also, the court considered it highly relevant that the patent's specification provided "that a drug-retaining substance '*must be used* in sufficient amount to ensure that the initial viscosity of the inner aqueous layer in the water-in-oil emulsion described hereinafter will not be lower than about 5000 centipoises . . . .'" *Id.* (emphasis in original) (citing U.S. Patent No. 5,476,663, col. 4, ll. 49-52 (filed Apr. 15, 1994)).

Teva argues that "the Federal Circuit [in *TAP*] held that the use of the word 'must' in the specification required a claim construction based upon an explicit disavowal of claim scope." (Def. Br. at 12.) Novartis rejects this interpretation, asserting that in *TAP*, the Federal Circuit "merely affirmed the . . . construction of the claim by properly reviewing the specification *to deduce* the meaning of a recited term." (Pl. Reply Br. at 3 (emphasis added).) Novartis fails to explain, however, the difference between "deduc[ing] the meaning of a recited term" (as Novartis describes *TAP*), and claim construction in light of "an explicit disavowal of claim scope" from the specification (as Teva interprets the opinion).

This Court is not certain that either party has fairly characterized *TAP*, and specifically what the Federal Circuit ascribed, to the scope of the claim at issue, the "must" language in the specification. Clearly, the court found that the "must" language, among other factors, contributed to the district court's claim construction. However, the extent to which this language was dispositive remains unclear. In any event, this Court finds that Teva has raised an interesting, and not so easily dismissed, comparison between *TAP* and the instant matter. The

'802 patent provides very clearly that "[b]enazepril and amlodipine are physically incompatible substances." ('802 patent, col. 3, ll. 51-52.) As such, "if incorporated into a single dosage form they *must* be kept physically separated." (*Id.* col. 3, ll. 52-53 (emphasis added).) Indeed, the express language of claim 1, by itself, does not limit its scope to "doses" where, in single dosage forms, the benazepril and amlodipine must be kept physically separated. However, when interpreting the claims, this Court cannot divorce itself from the language of the specification. The teaching and written description of the invention to be claimed in the '802 patent is persuasive intrinsic evidence that Novartis did not intend its invention to cover any method of treatment that included a "single dosage form" or "dose," (*see, e.g.*, '802 patent, col. 3, ll. 16, 52; col. 5, ll. 12, 23, 26; col. 6, l. 9), where the amlodipine and benazepril are not physically separated. (*See* Def. Br. at 11 n.4 (noting that the terms "'dose' and 'dosage' are used interchangeably in the art"); *see also NTP, Inc.*, 418 F.3d at 1310 (discussing the necessary "textual hook" in claim language to support a limiting construction).) Such reading is supported by the specification language cited above. As discussed above, the Court in *TAP* found comparable language of necessity, i.e., "must be used," as supportive of the district court's narrowing of a claim to include the relevant limitation from the specification. *TAP*, therefore, is illustrative of the scenario where a patent's claim may, at least in part, be construed--or its meaning "deduced"--based upon "mandatory" language in the specification, e.g., "must be used" or "must be kept." This construction appears to be consistent with *SciMed Life Systems* in which the Federal Circuit determined that "unequivocal" disclaiming language in a specification resulted in "a clear case of disclaimer of subject matter that, absent the disclaimer, could have been considered to fall within the scope of the claim language." *SciMed Life Sys.*, 242 F.3d at

1344; *see also Andersen Corp. v. Fiber Composites, Inc.*, 474 F.3d 1361, 1373 (Fed. Cir. 2007) (recognizing the "difficulty faced by district courts in trying to walk this tightrope."). Therefore, this scenario appears to represent an exception to ordinary prohibition of reading or importing a limitation from the written description into the claims. *See, e.g., SciMed Life Sys.*, 242 F.3d at 1340.

Teva also cites *Honeywell International, Inc. v. ITT Industries, Inc.*, as an example of a situation where a written description can disavow certain embodiments from the scope of a patent's claims. 452 F.3d 1312, 1319-20 (Fed. Cir. 2006). In *Honeywell*, the Federal Circuit construed the term "electrically conductive fibers" to "exclude carbon fibers from the scope of the '879 patent claims" because coverage of them was disavowed in the specification. *Id.* at 1320. Although carbon fibers were generally considered conductive, the court noted that the specification "demeaned the properties of carbon fibers," and noted further that "carbon fibers would not be suitable as 'electrically conductive fibers' in the claimed invention." *Id.* at 1319-20. According to the Federal Circuit, "[i]f the written description could talk, it would say, 'Do not use carbon fibers.'" *Id.* at 1320. Thus, the written description of the patent at issue had gone "beyond expressing the patentee's preference for one material over another." *Id.* Rather, "[i]ts repeated derogatory statements concerning one type of material are the equivalent of disavowal of that subject matter from the scope of the patent's claim." *Id.* Therefore, the court held that the patentee had disavowed subject matter that included "carbon fibers" from the scope of a claim where the express language of the claim did not provide such a limitation. *Id.*

Although, here, the '802 patent does specifically "demean" formulations where benazepril and amlodipine are not physically separate, the written description does announce that

the two components "are physically incompatible substances." ('802 patent, col. 3, ll. 51-52.) Rather than denouncement of a certain embodiment, this language appears to suggest *impossibility* of a certain embodiment. Thus, Teva's comparison of *Honeywell* to the instant matter, while not entirely analogous, is not unfounded. Although this Court is not prepared to say that the '802 patent's written description, if "it could talk, it would say" that single dosage formulations where benazepril and amlodipine are not physically separated necessarily are not included in the scope of the patent, Teva nevertheless presents a legitimate argument. The '802 patent provides, "[i]t is [an] object of the invention to provide combination products suitable for carrying out" "a synergistic combination therapy for the treatment of cardiovascular diseases and their sequelae which are responsive to antihypertensive therapy." ('802 patent, col. 2, ll. 14-19.) The mandatory language of the '802 patent suggests that doses that include combination products where benazepril and amlodipine are not physically separated necessarily are not "suitable for carrying out" "a synergistic combination therapy," and therefore are neither an object of the invention, nor covered under the scope of any clams, i.e., even claims that appear to have broader scope when read and interpreted independently.

The ultimate applicability of *TAP* and *Honeywell* to the instant matter remains an open question. However, this Court finds that Teva has raised a substantial question as to its infringement of the '802 patent in light of its proposed construction, and the support for such construction Teva finds in these cases.

Next, the Court considers an argument suggested by Novartis's invocation of the doctrine of claim differentiation with regard to claim 2. "In the most specific sense, 'claim differentiation' refers to the presumption that an independent claim should not be construed as

requiring a limitation added by a dependent claim." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) ("Indeed [35 U.S.C. § 112, paragraph 4] stresses that a dependent claim must add a limitation to those recited in the independent claim.") Therefore, "reading an additional limitation from a dependent claim into an independent claim would not only make that additional limitation superfluous, it might render the dependent claim invalid." *Id.* As noted above, claim 2 provides "[t]he method of claim 1 wherein the benazepril and the amlodipine are administered in a single dosage form, such that the benazepril and amlodipine *are physically separated from each other*." ('802 patent, col. 5, ll. 22-25 (emphasis added).) Novartis appears to argue that the physically separated requirement should not be read into independent claim 1 because that limitation is the sole basis for dependent claim 2. Novartis notes that the "'presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.'" (Pl. Br. at 16 (citing *Phillips*, 415 F.3d at 1315); *see also* Pl. Reply Br. at 2.)

Teva counters that such a claim differentiation presumption arises only if a proposed construction would create an independent and dependent claim with "identical" claim scope. (Def. Br. at 13.) Accordingly, Teva argues that the presumption does not apply here. This is because even under Teva's proposed construction of claim 1, which excludes coverage of single dosage forms that are not physically separated, "claim 1 would still cover both physically separated single dosage forms *and* the separate administration of benazepril and amlodipine by separate tablets." (*Id.* at 14 (emphasis in original).) As such, claim 2 is not "identical" in scope to Teva's proposed construction of claim 1 because claim 2 "is limited *only* to the physically

separated single dosage forms (just as claim 17[21] is limited to only separate administration of benazepril and amlodipine)." (*Id.* (emphasis in original).) According to Teva, claim 2 is therefore "narrower than, and properly dependent from, claim 1 under Teva's proposed claim construction." (*Id.*) Notably, Novartis does not refute this in its reply brief.

Teva also argues that the prosecution history of the '802 patent confirms that each claim, including claim 1, is limited such that where there is a single dosage form, the benazepril and amlodipine must be physically separated. Therefore, Teva asserts that the doctrine of prosecution disclaimer should apply. *Omega*, 334 F.3d at 1324 ("where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender"). As discussed above, the prosecution history of a patent often lacks the clarity of the specification, however, it remains helpful in understanding the meaning of the claim language. *Phillips*, 415 F.3d at 1317.

Specifically, Teva cites to Novartis's response to an Office Action which rejected *all* pending claims, including a claim identical to claim 1 of the '802 patent. In a December 30, 1999 non-final Office Action, the patent examiner rejected the proposed claims under 35 U.S.C. § 103(a) as being unpatentable, *inter alia*, over a prior art reference Maclean et al. (*J. Hum. Hypertension*, Vol. 2(2), 127-132 (Aug. 1988) ("Maclean"). (Woodard Decl. Ex. 28 at 531.) The examiner noted that Novartis's "claims appear to be drawn to methods and compositions for

[21] As noted above, claim 17 provides "[t]he method of claim 1 wherein the benazepril is administered in a first formulation which is free of the amlodipine and the amlodipine is administered in a second formulation which is free of the benazepril." ('802 patent, col. 5, ll. 1-4.)

treating a number of conditions including hypertension by administering benazepril and amlodipine in a weight ratio of 1:1 to 8:1." (*Id.*) With regard to the Maclean reference, the examiner noted that this piece of prior art "teaches administering captropril (an ACE inhibitor of the same class as benazepril) and amlodipine in a ratio of 5:1 for the treatment of hypertension." (*Id.*) According to the examiner, Novartis's "claims differ from the cited references [including Smith et al. (*FASB*, Vol. 5, No. 4, A851 (Mar. 11, 1991))] in claiming the use of the drugs in wide variety of conditions besides hypertension"; however, "[i]t would have been obvious to administer the drugs for the other conditions claimed because they are known to be complications associated with hypertension[,] . . . [t]hus, the claims fail to patentably distinguish over the state of the art as represented by the cited references." (Woodard Decl. Ex. 28 at 531-32.)

In a response dated May 23, 2000, Novartis raised several arguments to counter the examiner's obviousness rejection. (*Id.* at 574-78.) Shortly after this response, the examiner on July 20, 2000 issued a notice of allowability to claims that were almost identical to the claims presented to the examiner prior to the December 30, 1999 non-final Office Action.[22] Therefore, it is reasonable to assume that Novartis's May 23, 2000 arguments proved to be very important with regard to the patent application's ultimate allowance. For example, Novartis opined that "[t]he Examiner appears to be of the opinion that it would be obvious to one of ordinary skill in

[22] Apparently, Novartis agreed during a July 20, 2000 telephonic interview with the examiner to amend claim 19 to include "the partially closed language of 'consisting essentially of' and to a 'daily dose' composition to more closely parallel the language" of method claim 1. (Woodard Decl. Ex. 28 at 606.) Such amendments appear to have no impact on the issue at hand. Otherwise, the claim language presented to the examiner on December 30, 1999 appears to be identical to the claim language as it appears in the issued '802 patent.

the art at the time of Applicants' invention was made to modify Maclean's antihypertension therapy involving twice daily doses of captopril and a daily dose of amlodipine to achieve Applicants' invention." (*Id.* at 574.) Although the examiner's December 30, 1999 rejection was not so explicit in this regard, the Court agrees that Novartis's statement is a fair interpretation of the examiner's 103(a) rejection. Novartis subsequently argued that

> Maclean contains no teaching, suggestion or motivation to produce a pharmaceutical composition of benazepril in combination with amlodipine as disclosed by Applicant. There is certainly no motivation, teaching or suggestion in [Maclean] that such a combination would require that the ACE inhibitor and amlodipine be kept *physically separate* as taught by Applicants. As such, Applicants respectfully submit that Maclean does not render Applicants' invention obvious.

(*Id.* at 576 (emphasis added).) Based upon this argument, Teva asserts that Novartis "confirmed during prosecution that 'Applicants' invention' 'require[d]' and 'taught' that benazepril and amlodipine 'be kept physically separate.'" (Def. Br. at 14-15.)

Teva acknowledges that Novartis distinguished its invention from the Maclean reference "on a variety of bases." (*Id.* at 15 n.6.) However, Teva asserts that Novartis should nevertheless be held to this argument. As the Federal Circuit noted in *Anderson*:

> An applicant's invocation of multiple grounds for distinguishing a prior art reference does not immunize each of them from being used to construe the claim language. Rather, as we have made clear, an applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well.

474 F.3d at 1374 (citing *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1347 (Fed. Cir. 1998); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1477 n.1 (Fed. Cir. 1998) (when

applicant distinguishes a reference on multiple grounds, "any of those grounds may indicate the proper construction of particular claim terms.")). In other words, simply because Novartis *may* have been successful during prosecution if Novartis relied solely on other arguments to distinguish its invention from the Maclean reference, Teva argues that Novartis nevertheless should be held to *all* arguments that are presented to the examiner. Among these arguments, Novartis asserted to the patent examiner that Maclean provided "no motivation, teaching or suggestion . . . that such a combination would require that the ACE inhibitor and amlodipine be kept physically separate as taught by Applicants." (Woodard Decl. Ex. 28 at 576.) In the very next sentence, Novartis noted that "[a]s such, Applicants respectfully submit that Maclean does not render Applicants' invention obvious." (*Id.*) Here, the words "[a]s such" necessarily indicate that the immediately preceding discussion is relevant to why Novartis's invention is not obvious; and as discussed above, the immediately preceding discussion pertains to the combination form including the drug components when physically separated. Thus, although it may not have *needed* to make such an argument to avoid an obviousness rejection in light of Maclean, Novartis clearly intended the "physically separated" distinction to be considered by the examiner as a reason to remove the obviousness rejection.

Novartis, however, asserts that it did not disavow claim scope during prosecution of the '802 patent, and thus claim 1 cannot include a "physically separated" limitation. According to Novartis, the passage to which Teva cites is "only a short excerpt from an Office Action to support its argument," and that "[t]he passage taken out of context is merely an argument distinguishing a prior art reference from the fixed dosage form composition of claims 19-28." (Pl. Reply Br. at 3.) Novartis notes further that the passage "says nothing of a method of

treatment and is therefore irrelevant to any disavowal of the scope of method claim 1. Illustrating differences between an invention and cited prior art does not result in a disavowal of subject matter." (*Id.* (citing *Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1375 (Fed. Cir. 2004)).)

There are several weaknesses with Novartis's argument in this regard. First, Novartis asserts that the passage was intended to distinguish the Maclean reference from the fixed dosage form composition of only claims 19-28. However, the patent examiner's December 20, 1999 Office Action clearly rejected all of the proposed claims of the '802 patent, including the method *and* the composition claims. (Woodard Decl. Ex. 28 at 530.) In the reasoning for the rejection, the examiner made absolutely no distinction between the method and composition claims, and did not indicate that the Maclean reference was a basis for 103(a) rejection only with regard to the method claims. Thus it is inaccurate, and frankly misleading, for Novartis to say that the passage was "*merely* an argument distinguishing a prior art reference from . . . claims 19-28." (Pl. Reply Br. at 3 (emphasis added).)

Second, because the administration of the fixed combination dosage form, a preferred embodiment of the invention, ('802 patent, col. 3, ll. 1-4), is an example of the method of treatment covered by claim 1, it strikes this Court as inaccurate for Novartis to say that its response to the Office Action "says *nothing* of a method of treatment and is therefore *irrelevant* to any disavowal of the scope of method claim 1." (Pl. Reply Br. at 3 (emphasis added).) Again, this Court recognizes that prosecution disclaimer is not appropriate in all instances, for example "where the alleged disavowal of claim scope is ambiguous," or where remarks made by an inventor to overcome a rejection may be viewed "as amenable to multiple reasonable

interpretations." *Omega*, 334 F.3d at 1324 (citing *Northern Telecom*, 215 F.3d at 1293-95). Thus, Novartis's assertion that its response was directed solely to the scope of its fixed combination dosage claims and not to the method of treatment claims may ultimately carry the day. In the future, this Court may determine that when responding to the examiner's rejection, Novartis did not intend to limit the scope of any method claims in the '802 patent. Novartis correctly states that not every difference between an invention and prior art as cited in an Office Action response should result in disavowal of subject matter.

Nevertheless, this Court cannot at this time ignore Teva's argument that, prior to allowance, Novartis did not foresee any fixed combination dosage forms where the two drug components were *not* kept physically separate to be within the scope of *any* of the '802 patent's claims, including the method claim 1. In this regard, Teva has raised a substantial question with regard to infringement to the extent that the physically separated requirement may apply to all claims of the '802 patent.

(2) Meaning of the term "physically separated"

The term "physically separated" is not explicitly defined in the '802 patent. Therefore, in addition to determining whether the physically separated requirement should apply to all claims of the '802 patent with regard to single dosage forms--and, as already discussed, Teva has raised a substantial question in this regard--this Court must next determine what "physically separated" means in this context. This step is required in order to determine, preliminarily, whether Teva's products infringe the '802 patent.

Teva argues that based upon the claim language itself and the common meaning of the term in the art, the term "physically separated should be construed to mean 'there is a barrier

between the benazepril and the amlodipine to keep them apart.'" (Def. Br. at 16.) In other words, Teva asserts that the "physically separated" limitation, which is to be imputed to all claims of the '802 patent, mandates that benazepril and amlodipine always be kept apart by some physical barrier or layer. To support this position, Teva first attempts to parse the language at hand. Teva notes that "[t]he claims of the '802 patent do not merely require that the two active drugs be 'separated.' Rather, the claims go further and require that something 'physically' keep them apart." (*Id.*) Thus, Teva avers that the language of the claims themselves "require[s] that the benazepril and amlodipine be not only separated but *physically* separated." (*Id.* (emphasis in original); *see also* Hearing Transcript, May 21, 2007, at *22 (Teva's counsel noting that the patent's language "doesn't just say the substances amlodipine and benazepril need to be separate, it doesn't even say they need to be separated" but rather "[i]t says they must be physically separated").)

Although Teva does not explicitly say what the actual differences are between the terms "physically separated," and "separate" or "separated," Teva raises an interesting point. Indeed, the claims use the language "*physically* separated," and not any other alternative. Perhaps the claims would have a different meaning if there was no modifier of the word "separated," or if the claims included a different word to modify "separated," such as "chemically." Again, Teva does not elaborate on this issue. However, Teva's point is clear that the exact language that the patent applicant used to describe his invention must be considered. Here, the Court must consider "physical separation," possibly at the exclusion of other forms of "separation."

Next, Teva argues at length that the common meaning of the term physically separated "requires a barrier to keep the drugs apart." (Def. Br. at 17 (citing its own expert who asserted

that "[a] Skilled Formulator would understand 'physically separated' as it is used in the '802 patent to mean that there must be a barrier between the amlodipine and the benazepril that keeps them apart").)[23] Teva asserts that, possibly with the exception of a bi-layered tablet, five of the six methods identified in the '802 patent explicitly, and "unquestionably," require that a barrier exist between the drugs. (*Id.* at 17, 19.) As noted above, the written description of the '802 patent provides that physical separation

> may be accomplished in any of the myriad ways known in the art, such as bi-layered tablets, coated pellets of one agent incorporated into a tablet of the other, separately coated pellets of one agent in capsule together with powder of the other agent, each agent microencapsulated separately and then blended together for use in a tablet or capsule, use of a dual or multiple compartment transdermal device, etc. . . . For convenience purposes, a coated compressed tablet of benazepril together with amlodipine powder in a capsule has been found to be the most desirable oral form.

('802 patent, col. 3, ll. 53-66.) Morever, Teva argues, even a bi-layered tablet is not necessarily "limited to formulations with molecular contact, as Novartis suggests. Rather, 'bilayered tablets' *include* tablets with two drug layers and a barrier layer in between, or other methods to physically separate the two active ingredients." (Def. Br. at 17 (emphasis added).) Thus, according to Teva, even the inclusion of a bi-layered tablet in the list provided in the '802 patent does not offend its proposed definition of "physically separated" as requiring a barrier or layer.

Teva illustrates this point via several sources, including: (1) its own expert declarations that support the proposition that, in 1992, a skilled formulator "would understand that a bilayer

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[23] According to Teva, in internal documents, even Novartis used the claim term as Teva proposes it be construed. (Def. Br. at 17 n.7 (highlighting Novartis's statement that "[t]he film coating on Benazepril tablet physically separates the drugs," and that "[t]he tablet was coated with hydroxypropyl methylcellulose to serve as a physical barrier between the drugs.").)

tablet could include an inert layer between the two layers containing active ingredients"; (2) other unrelated U.S. patents that describe bi-layer tablets composed of two-drug layers "separated by a protective layer composed of . . . barrier materials";[24] and (3) deposition testimony of Novartis's expert who arguably conceded that it was possible to "manufacture [a bi-layer tablet] with an intervening layer," and who suggested that the patent's use of both terms "physically and incompatible . . . means you can't have [the two types of molecules] together." (*Id.* at 18.) Teva surmises that "in the context of the 'serious incompatibility' identified in the '802 patent, a person of ordinary skill would understand the reference to 'bilayered tablets' in the '802 patent to refer to the types of bilayer tablets that incorporate a barrier to keep the two active ingredients apart." (*Id.* at 18-19.)

According to Teva, its proposed interpretation of the term "physically separated" to require a barrier is dispositive in the instant matter, because, under this reading, Teva asserts that its products do not infringe any claim of the '802 patent. Specifically, Teva asserts that its generic Lotrel formulations intentionally include no barriers because Teva "specifically designed around the '802 patent by creating a formulation with physical contact between the two active ingredients." (*Id.* at 20.) In other words, Teva alleges that it managed to design a combination drug with amlodipine and benazepril where the two drug components did not need to be, and are *not*, physically separated. Indeed, Teva's counsel even asserted at the May 21, 2007, TRO hearing before Judge Cavanaugh that he had brought with him an example capsule for the Court to examine. Teva's counsel stated:

[24] Novartis rejects Teva's use of these references as not being prior art.

> You can open it up and see, it's a bunch of powder. They're not physically separated. . . . [I]f I dump out [Teva's] generic capsule, you'll just see powder. If I were to dump out [Novartis's] Lotrel, you'd see a tablet and powder. The capsule would open up, a tablet would fall out and powder would fall out. That's the implementation by Novartis and it is totally distinct from a formulation by Teva which obviously is not physically separated.

(Hearing Transcript, May 21, 2007, at *22-23.) The Court did not engage in this suggested "show-and-tell." More important, however, is Teva's contention that Novartis has not presented any evidence establishing that Teva's formulation has a physical barrier to keep the drugs apart. *See infra* 47 n.26. According to Teva's expert, who conducted a physical analysis of Teva's formulation, "in many regions, amlodipine besylate and benazepril hydrochloride are in intimate contact within the samples" "[a]t the surface level of the granule agglomerate." (Fernands Decl. Ex. 16 at 193; *see also id.* at 58-59 (testifying that there is no coating or barrier between the benazepril and amlodipine).)

Novartis does not directly contest Teva's linguistic distinction between the '802 patent's use of the term "physically separated," rather than just "separated" or some alternative. Instead, Novartis asserts that neither the patent's language nor the ordinary meaning of the term "physically separated" suggests a "barrier" requirement. Novartis rejects Teva's "offering that a 'barrier' is required to separate the amlodipine and benazepril" as a proper interpretation because, according to Novartis, Teva's interpretation is "based solely on an unfounded theory by its expert for this litigation." (Pl. Reply Br. at 6.) "To the contrary, the bi-layered tablet formulation demonstrates that a barrier is not required to 'physically separate' amlodipine and benazepril as the term is used in the '802 patent," because "[a] skilled artisan would know that a bi-layered tablet has only two layers *with molecular contact between the two drugs at the interface*." (*Id.* at

7 (first emphasis in original, second emphasis added) (citations omitted).) Rather "[m]ulti-layered tablets having two layers with an intervening 'barrier' layer, for example, would be labeled tri-layered.'" (*Id.*) Nevertheless, even under Teva's "flawed interpretation," Novartis asserts, Teva's products infringe "because the amlodipine and benazepril in Teva's formulation are separated by 'something physical,' including inert materials (excipients) which are added during Teva's manufacturing process and comprise the bulk of the formulation." (*Id.* at 7.)

According to Novartis, "[a] skilled artisan would understand that there are no absolutes," and that the purpose of the "physically separated" requirement "is to achieve stability through physical separation *sufficient to demonstrate the stability of the composition* for FDA approval." (Pl. Reply Br. at 5-6 (emphasis added).) Thus, Novartis would have this Court interpret the term "physically separated" to mean "[f]ormulations in which the benazepril and amlodipine are sufficiently physically separated so that the resulting pharmaceutical composition overcomes their incompatibility." (*Id.* at 5.) Under this definition, Novartis asserts that "molecular contact can exist between the two ingredients even if they are physically separated" so long as the single dosage form is sufficiently stable. (*Id.*)

Under this proposed construction of the term "physically separated," Novartis argues that Teva's products infringe claim 2. This is because "the method of manufacturing Teva's Products necessarily results in physical separation between the benazepril and the amlodipine." (Pl. Br. at 18.) According to Novartis,

> Teva performs numerous manufacturing steps that separate the two components so that the resulting formulation is a stable one in which the separation of the amlodipine and benazepril permits them to be compatible. For example, Teva's benazepril hydrochloride is formed into a wet granulate from a mixture that is mostly excipients, which

> necessarily act as a buffer between the amlodipine and benazepril. Amlodipine powder is similarly diluted by a separate mixture of excipients, then combined with the benazepril granulate later in the process.

(*Id.* at 18-19 (citations omitted).) In other words, Novartis asserts that despite its claims to the contrary, Teva's manufacturing process *does* separate the two components, primarily by diluting the drugs with other excipients. Therefore, even though the amlodipine and benazepril are combined "later in the process," according to Novartis, the drugs are still "physically separated" because the composition is sufficiently stable.

According to Teva, its formulation does not separate the two drug components at all. In fact, Teva asserts that it was a "discovery" on its part "that a combination of benazepril and amlodipine could be made that is not physically separated." (Def. Br. at 22.)[25] Moreover, Teva asserts that Novartis "has no evidence that Teva's formulation is stable (for FDA purposes) due to any 'physical separation.'" (*Id.* at 21.) Nevertheless, Teva assets that its formulation manages to maintain stability "by minimizing humidity with packaging rather than by 'physically separating' the two active drug components." (*Id.*) Thus, Teva refutes Novartis's claim that the drug components in Teva's formulation are separated in any manner. Additionally, Teva claims that even under Novartis's construction of "physically separated," Teva's formulation does not infringe because its generic versions achieve stability by virtue of its "special packaging" which is able to reduce moisture. (*Id.*) According to Teva, Novartis's infringement analysis turns on the supposed similarities between Teva's formulation and a "bi-layered tablet," yet "the law of

[25] Teva, however, does not describe its method of making a combination single dosage form where benazepril and amlodipine are not physically separated.

infringement compares the accused product with the claims as construed by the court," not the commercialized embodiment of the patentee. *Johnson & Johnson Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc).

As support for its proposed construction of the term "physically separated," Novartis first points to the "bi-layered tablets" example in the written description which, Novartis asserts, "inherently has molecular contact between the two components and provides this requisite compatibility." (Pl. Reply Br. at 6.) Novartis appears to argue that a bi-layered tablet comports with its proposed definition of "physically separated" because, as a general matter, bi-layered tablets may be stable, despite the limited molecular contact between the two drugs at the interface.

In addition to the bi-layered tablet, Novartis alleges that the other examples noted in the written description, all of which involve some form of coating, support its construction of the term "physically separated," i.e., that the composition design achieves sufficient stability. According to Novartis, this is because "skilled artisans understand that coatings do not provide an *absolute barrier*." (*Id.* (emphasis added).) That statement deserves repetition. According to Novartis, the examples noted in the patent's written description, which include a coating of some variety, supposedly support Novartis's construction of "physically separated" because "skilled artisans understand that coatings do not provide an *absolute barrier*." (*Id.* (emphasis added).) Here, and for the first time, Novartis uses the term "*absolute* barrier" to characterize what the patent's embodiments allegedly do *not* have. It may very well be true that none of the embodiments can be characterized as having an absolute barrier. But as far as this Court can tell,

nowhere does Teva propose a construction of the term "physically separated" to require an "absolute barrier." Rather, Teva asserts that "physically separated" merely requires "a barrier to keep the drugs apart." (Def. Br. at 17.) Presumably, Teva would agree that the examples in the patent which include coatings, i.e., the embodiments that are listed *after* the "bi-layered" tablet, all manage to include some sort of "barrier." However, that does not necessarily mean that the barrier must be "absolute." Thus, it would seem that in Novartis's attempt to shoot down entirely Teva's proposed construction of "physically separated" to include a barrier, Novartis asserts that even the embodiments that specifically include coatings cannot be characterized as having any "barrier" because "coatings do not provide an *absolute* barrier." (Pl. Reply Br. at 6 (asserting that "Teva must set forth 'highly persuasive evidentiary support' for adopting a construction that excludes the explicit examples and teachings set forth in the specification") (citation omitted).)

Although Novartis may be correct that Teva's proposed construction of the term "physically separated" to require a barrier is flawed, Novartis appears to take its argument at least one step too far. In other words, Novartis does not appear to benefit from the assertion that even the embodiments that include a *coating* would not qualify under Teva's proposed claim construction of "physically separated" because they do not provide an "absolute barrier." Clearly, Teva's most burdensome hurdle in asserting its proposed claim construction is the example of "bi-layered tablets" in the written description. That is, Teva's construction of "physically separated" would be a much easier sell if the bi-layered tablet was *not* included as an example embodiment in the '802 patent. This is because every other example embodiment in the patent includes some form of coating or separate encapsulation. But, alas, the '802 patent *does* include "bi-layered tablets."

At least intuitively, a bi-layered tablet need not necessarily include a coating or barrier between the drugs. However, this Court's intuition about the import of the term "bi-layered tablets," apparently, is not one shared by all parties. Teva vigorously argues that "'bi-layered tablets *include* tablets with two drug layers and a barrier layer in between, or other methods to physically separate the two active ingredients." (Def. Br. at 17 (emphasis added); *see also id.* ("A Skilled Formulator in 1992 would understand that a bilayer tablet *could* include an inert layer between two layers containing active ingredients.") (emphasis added) (citation omitted).) For its part, Novartis would call this a tri-layered or multi-layered tablet. In any event, it is notable that Teva seems to argue at times that a bi-layered tablet *must* include a barrier, and also at times that bi-layered tablets, as a class, *include* tablets with a barrier, i.e., that the bi-layered tablet *could* include a barrier. This is an important distinction because if a bi-layered tablet *must* include a barrier, then every embodiment described in the '802 patent would arguably include some form of barrier between the two drugs, and this uniformity would help inform this Court's construction of the term "physically separated." But even Teva is not consistent with this characterization. Accordingly, Teva's claim construction may be correct *if* a person having ordinary skill in the art, at the time of the invention, would have interpreted a bi-layered tablet necessarily to include a barrier, not merely that it *could*. If, however, a bi-layered tablet would have been understood by one having ordinary skill in the art to mean a family of single dosage forms, some of which do *not* have a barrier, then the strength of Teva's proposed construction of "physically separated" is substantially diminished.

Yet, at his juncture, Novartis's proposed claim construction of the term "physically separated" does not strike this Court as any more convincing. According to Novartis, a skilled

artisan would understand "physically separated" to mean a formulation that separates the amlodipine and benazepril enough to allow the drugs to overcome their incompatibility, i.e., "to achieve stability . . . sufficient to demonstrate the stability of the composition for FDA approval." (Pl. Reply Br. at 5-6.) However, Novartis points to nothing in the written description to support the proposition that a "physically separated" formulation need only be "stable," or that the standard for stability is that which would achieve FDA approval. To the contrary, the '802 patent explicitly announces that benazepril and amlodipine are *not* compatible substances and thus require physical separation. ('802 patent, col. 3, ll. 51-53 ("Benazepril and amlodipine are physically incompatible substances. Hence, if incorporated into a single dosage form they must be kept physically separated.").) This language does not appear to impart a "stability" requirement. Nevertheless, Novartis asserts that a skilled artisan would interpret "physical separation" to mean merely that which is "stable." But what if one managed to produce a combination drug of amlodipine and benazepril where there was no apparent *physical* separation, but yet the components were sufficiently stable? This is essentially what Teva purports to have accomplished. Thus, if the two drugs in single dosage form lack *any* separation, much less *physical* separation, yet the combination formulation is somehow sufficiently stable to achieve FDA approval, how would that example infringe the '802 patent's claims without eviscerating the "physically separated" limitation according to Novartis's construction?

This Court finds, at this preliminary stage, that both parties' proposed constructions of the term "physically separated" miss the mark. That is, Novartis's assertion that "physically separated" is a function of stability, or an arrangement whereby the resulting pharmaceutical composition overcomes the components' incompatibility, does not appear to be sufficiently

supported by intrinsic or extrinsic evidence. Simply put, this construction appears to be too broad, and encompasses more embodiments than the limitation "physically separated" likely permits. In the same vein, Teva's proposed construction of "physically separated" to require some barrier between the two drugs also appears to fail to find sufficient support in the intrinsic or extrinsic evidence provided to this Court. That construction, it would seem, is too narrow, and possibly limits the breadth of the '802 patent's claims more than the "physically separated" limitation permits.

As discussed above, an infringement analysis is generally a two-step process: (1) construction of the patent's claims to ascertain their proper scope, and (2) comparison of the properly construed claims to the allegedly infringing products to determine whether the products fall within the scope of the claims, literally or under the doctrine of equivalents. *Cybor Corp.*, 138 F.3d at 1466. In the instant matter, it has become increasingly apparent to this Court that the outcome of this analysis, prior to a full Markman Hearing, is not foreordained. That is, with regard to the first step, both Novartis and Teva propose diametrically opposed constructions of the term "physically separated." Regarding the second step, both parties argue that even under their adversary's construction, they would win on the issue of infringement. Thus, the parties recognize no middle ground with regard to either of the two prongs of the infringement analysis. Indeed, this Court believes the truth may lie somewhere in the middle. That is, the term "physically separated," when properly construed, likely has a scope somewhere in-between the overly broad and narrow constructions proposed by the parties. Where along the possible spectrum of construction this Court will ultimately land following a Markman Hearing, the Court is unable to say at this preliminary stage. In the meantime, there is no likelihood that Novartis

will show that Teva's products infringe properly construed claims of the '802 patent.[26]

iv. Doctrine of Equivalents

Even if this Court finds that Teva does not literally infringe any claims of the '802 patent, Novartis asserts that, under Novartis's proposed construction of the physically separated requirement, Teva infringes under the doctrine of equivalents. Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). In the seminal case, *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, the Supreme Court reiterated that infringement by equivalency exists if the accused product "performs substantially the same function in substantially the same way to obtain the same result." 339 U.S. 605, 608 (1950) (citation and internal quotation marks omitted). The Supreme Court has observed that such patent protection is required because "the nature of language makes it impossible to capture the essence of a thing in a patent application. . . . [It] may not capture every nuance of the invention or describe with complete precision the range of its novelty." *Festo*, 535 U.S. at 731.

Novartis's argument that Teva's generic versions of Lotrel would meet the physically

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[26] Although Novartis submitted several expert reports to this Court that challenged the experiment, analysis and findings of Teva's expert, Andrew M. Hirt--including the assertion that amlodipine besylate and benazepril hydrochloride are in intimate contact within Teva's samples at the surface level of the granule agglomerate--it is notable that Novartis does not point to, and this Court cannot find, any competing expert report that includes a scientific study of Teva's products. Thus, this Court is effectively left with no alternative expert analysis that describes how the amlodipine and benazepril exist within Teva's allegedly infringing products.

separated requirement by equivalents does not weigh in favor of a preliminary injunction at this time. Novartis assumes that "amlodipine and benazepril are incompatible and therefore any pharmaceutical formulation must overcome this incompatibility in order to meet FDA stability requirements." (Pl. Br. at 20 (citation omitted).) Because Teva's generic versions "are single dosage forms that must meet FDA requirements for stability," Novartis asserts, "contact between the amlodipine and benazepril in Teva's Products must be the equivalent of 'physically separated.'" (*Id.*) However, Novartis's equivalency argument is premised solely on its proposed claim construction of the physically separated requirement, a construction of which this Court has already expressed skepticism. Although not dispositive, Novartis does not present any argument for infringement by equivalency based upon Teva's proposed construction of the physically separated requirement. Because it remains an open question what the term "physically separated" means with regard to the '802 patent, this Court is unable at this time to determine whether Teva's allegedly infringing products perform their desired result in "substantially the same way" as the '802 patent. Thus, Teva has raised a substantial question as to whether it infringes the '802 patent under the doctrine of equivalents.

* * *

To demonstrate a reasonable likelihood of success on the merits, Novartis must show, *inter alia*, that it will likely prove that Teva infringes at least one claim of the '802 patent. For the reasons discussed above, this Court is not persuaded that either parties' proposed constructions of the term "physically separated" are likely to be sufficiently supported by intrinsic or extrinsic evidence. Therefore, a substantial question remains whether Teva's formulations infringe any claim of the '802 patent when the term "physically separated" is

properly construed. In the future, this Court may be called upon to make a final, proper construction of this term. Currently, however, there remains a substantial cloud of ambiguity over the meaning of this particular limitation. For the purposes of the instant preliminary injunction motion, this Court need not construe the term "physically separated." It suffices to say, however, that Novartis has failed to demonstrate that Teva's non-infringement defense lacks substantial merit. Therefore, Novartis has failed to carry its burden of showing that it will likely prove that Teva's formulation infringes an '802 patent claim.

b. Invalidity

In light of this Court's conclusion that Teva has raised a substantial defense with respect to infringement, this Court need not, and will not, consider Teva's other arguments with regard to infringement (the "daily dose" limitation) or invalidity (§ 103(a) obviousness).

2. Irreparable Harm If the Injunction Is Not Granted

Turning now to the second factor in the preliminary injunction analysis, Novartis must demonstrate that it will suffer irreparable harm if an injunction is not granted. *Amazon.com*, 239 F.3d at 1350. Both parties acknowledge that irreparable harm is presumed when a patent owner makes a "strong showing" of patent validity and probable infringement. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005); *Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1271 (Fed. Cir. 1985). Ultimately, Novartis may prove that Teva infringes the '802 patent. But for the purposes of the instant preliminary injunction motion and as set forth above, Novartis has neither made a "strong showing" of probable infringement nor has it demonstrated a reasonable likelihood of success on the merits with regard to infringement. Therefore, Novartis is not afforded the presumption of irreparable harm. That, however, does not end the inquiry.

Novartis repeatedly argues that failure to enjoin Teva's sales of its generic versions of Lotrel would result in irreparable harm that is not compensable by monetary damages. Novartis asserts that a launch of generic versions of Lotrel would cause immediate and severe harm to Novartis in the form of "lost sales revenue, lost market share, irreversible price erosion, lost business and growth prospects, and lost research opportunities." (Pl. Br. at 37.)

According to Teva, all of Novartis's asserted harms "are purely economic and thus not irreparable." (Def. Br. at 47.) Teva first challenges Novartis's assertion that a launch of a generic verison of Lotrel would cause immediate and severe harm. Apparently, amlodipine and benazepril are now both available as separate generic products, i.e., third-party competition already exists in the market. (*Id.*) Therefore, Teva asserts that "[a]t least part of the harms identified by Novartis will arise from the already existing generic competition, not from the addition of Teva's product." (*Id.*)

Teva's primary argument, however, is that Novartis's predicted lost sales revenue and lost market share are classic examples of harms that are monetarily compensable. (Def. Br. at 48.) Although such damages calculations may prove very complicated, Teva argues that such calculable economic losses do not justify "the extraordinary relief of an injunction prior to trial." (*Id.*) Indeed, Novartis submitted to this Court an expert report that estimated a specific value of lost sales and lost profits to Novartis if Teva enters the market prior to the expiration of the '802 patent and is found to infringe. (*Id.* at 49 (citing Maness Decl. March 22, 2007, at ¶ 12).) Teva's expert challenges the calculations performed by Novartis's expert as "unreliable and misleading" because it "ignore[s] several crucially important considerations," such as the impact of Novartis's own possible entry into the market with new combination drugs. (Addanki Decl., Nov. 15, 2006,

at *1; *see also id.* at *4 (noting that Novartis's expert "appears to assume that, but for the entry of generic Lotrel, the market for Lotrel would continue to grow as it has, or at the very least, not decline").). More important, however, is Teva's expert's criticism that Novartis's expert "himself estimates annual lost profits associated with" lost sales and market share and lost growth opportunity. (Addanki Decl., Apr. 13, 2007, at *4.) "Therefore, [Novartis's expert] already acknowledges that lost profits are calculable." (*Id.*) Novartis's expert responded to this criticism by noting that these "calculations are based on [2006] sales, do not include future growth in Lotrel sales, and . . . are not intended to be a definitive measure of damages due to lost sales, but merely demonstrative." (Mannes Decl. April 24, 2007, at ¶ 5.)

This Court is not prepared to settle the battle of the economic experts today, nor should it. But where a dispute between the parties' experts regarding Novartis's potential losses involves the discussion of specific--although estimated--monetary values, it appears to cut against Novartis's claim that its losses would be "unquantifiable with any degree of specificity." (Pl. Reply Br. at 24.) The Court acknowledges that the report submitted by Novartis's expert was not intended to be a *definitive* measure of damages. However, it was *a* measure of damages, if only an estimation or "demonstrative." Therefore, although Novartis's damages might be significant, and the complexities and uniqueness of the pharmaceutical industry might make such calculation an arduous task, Novartis's own expert appears to support Teva's assertion that such damages are calculable. The apparent corollary to this statement is that calculable damages may be reparable by money damages.[27] *See, e.g.*, *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991)

[27] Teva indicates that if it had to, it would be able to "afford to pay any damages that may arise." (*Id.* at 49 (noting that "Teva is the world's largest generic pharmaceutical company, and its ability to pay any damage award is demonstrated by a variety of financial measures").) Yet

("[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial. Indeed, the district court's reliance on possible market share loss would apply in every patent case where the patentee practices the invention.") (citation omitted).

Teva also challenges Novartis's assertion that a premature launch of a generic Lotrel product would result in irreversible price erosion and lost business and growth prospects. (*See, e.g.*, Maness Decl., Mar. 22, 2007, at ¶ 17.) Generally, Teva argues that Novartis's experts failed to take into account the effect of several factors, such as the existence of generic amlodipine on the market, in the estimation of lost growth opportunities. (Def. Br. at 49-50 (noting that Novartis's expert "ignores the fact that the market for drugs may expand upon the launch of a generic.").) Teva also asserts that Novartis's claims of price erosion are "mere speculation," and, even if price erosion occurs, it is "a purely economic harm . . . that could be calculated." (*Id.* at 50-51.) Novartis's only response is that Teva's assertions are "contrary to a *legion* of cases granting preliminary injunctions based on precisely" such factors as "lost sales, market share, and price erosion." (Pl. Reply Br. at 24 (emphasis added) (citing *Sanofi-Snythelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381-83 (Fed. Cir. 2006)).) Although there might exist many examples of courts granting preliminary injunctions where these factors were present, it does not necessarily follow that the possibility of such factors in such matters *demanded* a preliminary injunction. Similarly, the possibility of these factors in the instant matter does not alone demand a preliminary

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Teva's confidence in its ability to pay monetary damages, if necessary, is not dispositive. *See Polymer Techs. Inc. v. Bridwell*, 103 F.3d 970, 975 (Fed. Cir. 1996); *Roper Corp.*, 757 F.2d at 1269 n.2 (rejecting "the view that an alleged infringer's 'ability to compensate' must end a court's inquiry" with regard to irreparable harm).

injunction, especially where such losses, by all measure, appear to be calculable.

Finally, Teva challenges Novartis's argument that without the profits lost to generic sales of Lotrel, Novartis would suffer "lost research opportunities, and would impede the development of new therapeutic applications for Lotrel and possibly new innovative treatments for hypertension." (Pl. Br. at 38.) In other words, Novartis claims that lost profits from the sale of Teva's generic versions of Lotrel would reduce Novartis's ability to fund research and development ("R&D") of new therapeutic applications of Lotrel and other innovative treatments for hypertension. Teva argues that Novartis "cannot prove irreparable harm merely by asserting that it would use the money productively for research and development." (Def. Br. at 51.) According to one of Teva's experts, Novartis's argument "might make sense in the context of a small firm for which the patented product represents a large portion of its revenues and profits. . . . However, this is not the case for Novartis [where] in 2006, its net sales were greater than $36 billion, and its gross profits were over $26 billion." (Addanki Decl., Apr. 13, 2007, at *9-10 (citation omitted).) Whether this expert's assessment is or is not true, this Court is guided by *Eli Lilly & Co. v. Am. Cyanamid Co.*, in which the Federal Circuit noted:

> If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief. Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits.

82 F.3d 1568, 1578 (Fed. Cir. 1996). Here, Novartis has not even shown a likelihood of success on the merits. Thus, any potential or attenuated damage to Novartis's ability to fund R&D does

not compel entitlement to a preliminary injunction.

For the reasons discussed above, this Court finds that Novartis has not demonstrated that it will suffer irreparable harm if an injunction is not granted to prevent Teva from marketing its generic versions of Lotrel.[28] Should it prevail on the merits, Novartis's harm may ultimately be quite substantial. However, due in part to Novartis's own expert's efforts to calculate (preliminarily) the potential pecuniary harm to Novartis, this Court is not persuaded that such harm is incalculable. *See, e.g., eBay, Inc. v. Bidder's Edge, Inc.*, 100 F. Supp. 2d 1058 (N.D. Cal. 2000) (noting that "potentially calculable monetary damages are not generally a proper foundation for a preliminary injunction").

3. Balance of Hardships

When evaluating the balance of hardships, a "court must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." *Hybritech*, 849 F.2d at 1457.

According to Novartis, the balance weighs in favor of granting its motion for a preliminary injunction because Novartis would suffer "substantial and irreparable" harm. (Pl. Br. at 39.) Novartis argues that, when Teva filed its ANDA, it was fully aware of the '802 patent. By filing the Paragraph IV Certification, Novartis assets, Teva "fully appreciated the risk it took

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[28] This Court hastens to add that Teva has, in fact, already launched its generic versions of Lotrel, albeit for only a short period of time. Although Teva was temporarily restrained from further sales within approximately 24 hours of first hitting the market, even Novartis admits that Teva's entry has *already* resulted in substantial harm. (*See, e.g.*, Pl. Br. in Support of a TRO, May 21, 2007 (before the recall was vacated, noting that, absent a recall, the "existing supply of Teva's Products already in the distribution chain" would "substantially and irreparably harm" Novartis).

in seeking to introduce a directly competitive, infringing product. Therefore, to the extent Teva's hardship results from its obligation to stop infringing Novartis'[s] patent, Teva can only blame itself." (*Id.*) Novartis also asserts that Teva's hardship is "minimal because a preliminary injunction would merely preserve the status quo." (*Id.*)

Teva responds that a preliminary injunction would deprive it of "profits it might have earned" but for the injunction. (Def. Br. at 52.) Thus, Teva does not appear to point to any present damages it would suffer by virtue of a preliminary injunction, but rather to future harm. If a preliminary injunction is granted, Teva argues that its potential lost earnings may be exacerbated by the possible market entry by Novartis and its subsidiaries of new combination therapies and authorized generic versions of Lotrel before Teva's generic versions can get on the market. (*Id.* ("In other words, the grant of a preliminary injunction might allow Novartis to capture both the branded market as well as the generic market.").) This may or may not be true. Nevertheless, compared to the potential loss Teva would suffer if it is unable to capitalize on its generic versions of Lotrel, Novartis's loss of value of the '802 patent is likely greater. *See, e.g.*, *Glaxo Group Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003) ("The district court did not clearly err in finding that, without the preliminary injunction, Glaxo would lose the value of its patent while Apotex would only lose the ability to go on to the market and begin earning profits earlier.").

Although Teva did not raise this issue in its briefing, this Court acknowledges a more recent development in this matter that, arguably, supports Teva's argument pursuant to this factor of the preliminary injunction analysis. Contrary to Novartis's assertion that a preliminary injunction would "merely preserve the status quo," (Pl. Br. at 39), the circumstances with regard

to Teva's ANDA application have materially changed since the parties submitted briefing on the matter. As noted above, on May 18, 2007, Teva was granted final approval by the FDA to market its generic versions of Lotrel. Additionally, pending further order of this Court, the parties remain prospectively and temporarily restrained from selling authorized or unauthorized generic versions of Lotrel within their possession, custody and control. This temporary restraining order also applies to any of the parties' subsidiaries. As such, Teva remains enjoined from marketing and selling any more of its generic versions of Lotrel, which had been granted final approval. As the first generic filer, the FDA also granted Teva a "180-day exclusivity period" during which time the FDA is precluded for 180 days following Teva's "first commercial marketing of the drug" from granting final approval to any other ANDA applicant that seeks to market its own generic versions of Lotrel. 21 U.S.C. § 355(j)(5)(B)(iv). Teva asserts that its "180-day exclusivity period" began on Friday, May 18, 2007, when it commercially launched its products. (Teva's Opposition Br. to Novartis's Mot. to Vacate or Modify the TRO, May 21, 2007, at *15-16.) This Court is mindful that if Teva were to be enjoined from selling its generic products until a trial on the merits, Teva may lose a large portion, or even the entirety, of its exclusivity period.

However, the urgency created by Teva's launch and the commencement of the exclusivity period does not favor Teva's position entirely. By launching its generic Lotrel products on May 18, 2007, immediately after receiving final approval from the FDA, during the pendency of this litigation, and, more specifically, during the pendency of Novartis's motion for a preliminary injunction, Teva knew that it was proceeding at its own risk. Although Teva asserts that it has strong arguments as to the invalidity or its noninfringement of Novartis's '802 patent, Teva knew

the '802 patent, which covers Lotrel, currently remains valid. Teva launched its products without first notifying the Court, or providing Novartis sufficient notice to obtain a TRO prior to the launch. Indeed, Teva was under no obligation to provide such notice. Nevertheless, given the timing of events as described above, the injunctions that have already inhibited Teva, in one form or another, from selling its approved generic products since May 19, 2007, and a preliminary injunction heretofore, should have come as little surprise. By its very nature, launching generic products "at risk," has risks.

On the other hand, Novartis also contributed significantly to its current predicament. Novartis originally filed the instant patent infringement action on September 16, 2004. Novartis *could* have brought the pending preliminary injunction motion as early as July 11, 2006, when Teva received preliminary approval for its generic drug application. Instead, Novartis waited until March 27, 2007, to file its motion. This motion was filed more than a month after the statutory 30-month stay expired, on or about February 6, 2007, during which time the FDA could not grant Teva final approval. 21 U.S.C. § 355(j)(5)(B)(iii). This motion was also filed only two days after the '303 patent expired. The expiration of the '303 patent provided the FDA with the earliest date upon which it could grant Teva final approval. 21 U.S.C. § 355(j)(5)(B)(ii). Thus, in a March 22, 2007, letter to the parties, this Court was critical of Novartis for bringing its request for emergent relief on such an expedited basis. This Court noted that Novartis was well aware of the expiration dates of the '303 patent and the 30-month stay for many years. At Judge Cavanaugh's TRO hearing, Novartis's attorney even acknowledged that it could have brought its preliminary injunction motion prior to the passage of these important dates, yet Novartis did not. (Hearing Transcript, May 21, 2007, at * 35.)

In failing to bring the instant preliminary injunction motion earlier, Novartis avoided an early determination by this Court as to the validity of the '802 patent or Teva's infringement of it. Yet, by failing to bring the preliminary injunction earlier, or by failing to enter into a consent decree with Teva to not market its generic, Novartis elected not to take certain steps to prevent Teva's products launch prior to this Court's ruling on a motion for a preliminary injunction.

Nevertheless, Teva's inability to hit the market with its generic products to begin earning profits earlier, and to capitalize on the 180-day exclusivity period that has already begun, is not equivalent to the likely harm Novartis would suffer. The '802 patent will not expire for approximately another ten years, on December 19, 2017. (Fernands Decl., May 21, 2007, Ex. G, at *2.) Thus, Novartis has a great interest in enforcing the '802 patent throughout its remaining useful, and substantial income-earning, life. Notwithstanding this Court's doubts as to Novartis's likelihood of success on the merits, as discussed above, it is apparent to this Court that a balancing of the parties' hardships tips in Novartis's favor.

4. Public Interest

Novartis vigorously argues that the public's interest is best served by protecting valid patent rights, and that "Teva's desire to sell lower-priced generic products 'does not justify infringing a patent,' nor does it make such an infringement in the public interest." (Pl. Br. at 41 (citing *Pfizer, Inc.*, 429 F.3d at 1382).) According to Novartis, "[t]he law does not recognize price-cutting by infringers or disregarding patent rights as 'public interests' worth considering." (Pl. Reply Br. at 25 (citations omitted).) Teva responds that "no public interest is served by enforcement of invalid patents or using patents to prohibit sales of non-infringing products." (Def. Br. at 53.) "Plainly, the public favors distribution of low cost pharmaceuticals over the

extension of monopoly pricing by means of invalid patents that are not infringed." (*Id.*)

This Court acknowledges that the public's interest in low cost generic alternatives must be balanced by the public's interest in the protection of patent rights. *See Glaxo Group Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003) (non-precedential opinion) ("To the extent that the public interest favors generic competition, it is also the public's strong interest to protect patent rights, especially in view of [plaintiff's] likelihood of success with respect to infringement and validity of the patent."); *see also Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983) ("Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research."). This Court has not addressed Novartis's likelihood of success that the '802 patent will be found valid. As noted above, an issued patent is presumed valid at all stages of litigation, including the preliminary injunction stage. 35 U.S.C. § 282; *see also Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1988). However, Teva has raised a substantial question as to its likely infringement of the '802 patent. Therefore, *if* Teva is found not to infringe the '802 patent--even if the '802 patent is ultimately determined to be valid--then the public's strong interest to protect patent rights would not be furthered substantially by a preliminary injunction on Teva's non-infringing products. Although in the course of litigation the claims of the '802 patent may be further limited to Novartis's detriment, this Court's failure to enjoin a possibly non-infringing generic versions of Lotrel would not best serve the public's interest. *See Pfizer, Inc.*, 429 F.3d at 1382 (noting that "the statutory framework under which [the defendant] filed its ANDA," in part, "does seek to make low cost generic drugs available to

the public"). Thus, Novartis has failed to carry its burden of showing that a preliminary injunction would have a favorable impact on the public interest.

III. CONCLUSION

Although Novartis may suffer more hardship than Teva if the motion for a preliminary injunction is denied, Novartis has failed to carry its burden with regard to the three other prongs of the preliminary injunction analysis: a reasonable likelihood of the success on the merits, irreparable harm, and the impact on the public interest. *Amazon.com*, 239 F.3d at 1350 (noting that a "district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested"). Simply because Novartis's hardship may be greater if a preliminary injunction is not imposed, it does not necessarily follow that Novartis is entitled to such an extraordinary remedy. Indeed, the strength of the other factors weigh against such relief.

IV. ORDER

For the foregoing reasons, all existing restraining orders are VACATED (Docket Nos. 56, 58 and 64). Novartis's motion for a preliminary injunction (Docket No. 54) is DENIED.

Newark, New Jersey
Dated: June 11, 2007, 1:00 p.m.

/s/ Harold A. Ackerman
U.S.D.J.